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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,870	01/28/2002	Marcus Hartmann	P67083US0	4106

136 7590 09/20/2004
JACOBSON HOLMAN PLLC
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WASHINGTON, DC 20004

EXAMINER

AKHAVAN, RAMIN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,870

Applicant(s)

HARTMANN ET AL.

Examiner

Ramin (Ray) Akhavan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of a preliminary amendment, filed 09/04/2001, amending claims 3-5 and 9, adding new claim 10. Claims 1-10 are pending and under consideration.

Election/Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required to elect a single invention to which the claims must be restricted. The groups are as follows (each group designated with a roman numeral):

- I. Claim 7, drawn to a peptide having the sequence of SEQ ID NO: 2.
- II. Claim 8, drawn to a nucleic acid having the sequence of SEQ ID NO: 1.
- III. Claims 1-6 and 10 drawn to use of a nucleic acid for homologous or heterologous expression of recombinant proteins and peptides.
- IV. Claim 9, drawn to use of a peptide for homologous or heterologous expression of recombinant proteins and peptides.

The inventions listed in groups I-IV do not related to a single general inventive concept under PCT Rule 13.1 because under Rule PCT 13.2, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same corresponding special technical features (i.e. technical features that define a contribution which each of the inventions considered as a whole makes over the prior art). Production of recombinant β -hexosaminidase in a ciliate (i.e. claim 1) does not define a contribution that the inventions as a whole make over the prior art. (See, Hunseler et al. Biochem. J. 1988; 252:837-42; teaching recombinant β -hexosaminidase production in *Tetrahymena thermophila*, a ciliate;

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cited in the Info. Disc. Statement). Therefore unity of invention does not exist as between the various groups of inventions.

Group I is drawn to a particular amino acid sequence, a structure that is not shared by Group II, nucleic acid structures. There is not shared technical feature between peptides and nucleic acids, as each inheres a unique structure and correlates to distinct functions (e.g. eliciting an immune response to raise antibodies versus hybridization reactions). Therefore, each is a biologically distinct structure, with a distinct special technical feature. It logically follows, that processes incorporating distinct structures do not share the same special technical features. The protein of Group I is not a necessary predicate, where a use incorporates nucleic acid structures and not peptides, and vice versa (nucleic acids not necessary for a use requiring a peptide; Group).

As between group I and IV, Group IV's special technical feature is use of the peptide in expression of recombinant proteins. In other words, the particular use in recombinant cloning is the special technical feature, which clearly would not be shared in disparate processes incorporating the same peptide. For example, the peptide could be used in a process to raise antibodies, which would necessarily constitute a distinct special technical feature in and by itself. Put another way, the claimed use defines the special technical feature, and since the peptide in this case can be used in various biologically and patentably distinct uses, then Group I and IV are not so linked to satisfy unity of invention.

Conclusion

The claims encompass four distinct inventions, which are subject to a restriction requirement. Applicant must elect a single group (I-IV) in response to this action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday-Friday, from 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD, can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center at 866-217-9197 (toll-free).

Respectfully submitted,

Ray Akhavan/AU 1636


GERRY LEFFERS
PRIMARY EXAMINER